S.M

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,713	06/30/2000	Hideo Ago	SHIM-007	2056

22852 7590 06/14/2004

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/608,713	AGO ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36,38 and 39* is/are pending in the application.

4a) Of the above claim(s) *19-29,32 and 34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31,33,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19-36,38 and 39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments filed March 23, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The cancellation of claim 37 has been acknowledged.

3. Claims 30, 31, 33, 38, and 39 are examined on the merits.

PRIORITY

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). However, foreign applications JAPAN 11-188630, filed July 02, 1999, and JAPAN 11-192488, filed July 07, 1999 do not disclose the three-dimensional structural coordinate of an NS5B HCV polymerase. It is noted the foreign applications are directed to a generic HCV polymerase while the instant claimed invention is directed to NS5B HCV polymerase. Therefore, the instant application does not receive the priority benefit of foreign applications JAPAN 11-188630, filed July 02, 1999, and JAPAN 11-192488, filed July 07, 1999.

RESPONE TO ARGUMENT

5. Applicant argues that the Office has mischaracterized Applicant's benefit of priority after the acknowledgement of Applicant's claim for foreign priority under 35 U.S.C. §119 (a)-(d). Applicant's argument has been fully considered and found to be unpersuasive as discussed below. It is re-iterated that Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d)

has been acknowledged. The above acknowledgement simply recognizes that Applicant has claimed foreign priority under 35 U.S.C. 119(a)-(d). However, said statement does not indicate that the priority benefit to foreign applications JAPAN 11-188630, filed July 02, 1999, and JAPAN 11-192488, filed July 07, 1999, has been granted to the instant application.

6. The foreign priority benefit has not been granted because the foreign applications are directed to a generic HCV polymerase while the instant claimed invention is directed to a limited NS5B HCV polymerase. Therefore, the instant application does not receive the priority benefit of foreign applications JAPAN 11-188630, filed July 02, 1999, and JAPAN 11-192488, filed July 07, 1999.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 30, 31, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

9. NEW MATTER REJECTION.

10. This rejection is necessitated by Applicants amendments.

11. Specific to claim 30, last two lines; the newly added limitation "polypeptide inhibits...by binding to said active and/or RNA binding cleft of said HCV polymerase" has not been found in the instant specification. It is noted that the pointed to support (page 12, lines 7-22)

discloses the determination of "Complementary of a test compound with an active site and/or RNA binding cleft of the polypeptide...visualizing the binding stability." Further, the previously amended claim 30, last two lines, filed May 23, 2003, recites "wherein a test compound that is complementary...is a HCV polymerase inhibitor." The previously amended claim 30, filed May 23, 2003, does not recites any limitation wherein the inhibition of the HCV polymerase by a compound requires a binding action to occur for said compound to "inhibit" said polymerase. Additionally, the pointed to disclosure provides support for determining complementary of a test compound with an active site and/or RNA binding cleft of the polypeptide by binding stability which is different from the limitation of "inhibits a HCV by binding". The pointed to disclosure does not provide support for the limitation of "polypeptide inhibits...by binding to said active and/or RNA binding cleft of said HCV polymerase." Claims 31 and 38 are rejected for being dependent from claim 30.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 30, 31, 33, 38, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystal structure of HCV polymerase using $NS5B_{570, 544, 536 \text{ and } 531}$, does not reasonably provide enablement for all HCV polymerases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

14. This rejection is maintained with respect to claims 30, 31, 33, 38, and 39 as recited in the previous Office Action, mailed December 24, 2003.

RESPONSE TO APPLICANT'S ARGUMENT

15. Applicant's argument of the specification fully enables the claimed invention because Applicant's has amended the claims to recite HCV polymerase polypeptides comprising sequences corresponding to $NS5B_{570, 544, 536, and 531}$. Applicant's argument has been fully considered and found to be unpersuasive as discussed below. It noted that Applicant has amended claims 30 and 33 to recite "X is...531, 536, and 570 of NS5B" and "X' is...531, 536, and 544 of NS5B", respectively. However, the newly added limitations above do not limit the claimed invention to what is enabled by the instant specification. For example, claim 30, lines 12-13; and claim 33, lines 8-9, recite the limitation "Y...is not derived from NS5B" which is not enabled by the instant specification.

REJECTION RE-ITERATED

16. It is re-iterated that applicants have disclosed information to enable one skilled in the art to make a usable crystal of the HCV polymerase using $NS5B_{570, 544, 536 and 531}$ (Examples 1-3, Pages 20-27). However, the breadth of claims 30, 31, 33, 38 and 39 includes HCV polymerase $NS5B_{570, 544, 536 and 531}$ crystals and modified versions of HCV polymerase crystals, which go beyond the crystals cited in Examples 1-3 ($NS5B_{570, 544, 536 and 531}$).

17. It is well documented that protein crystallization is in essence a trial-and-error method, and the results are usually unpredictable (Drenth, J.). Further, as recently as November 1, 2002, Science published a New Focus article depicting the current state of the art for protein crystallization that supports the unpredictability of the art. Protein crystallization is still a

trial and error process because the current technology for producing protein for the crystallization process is unpredictable, which results in high failure rate for proteins that are being crystallized. Therefore, researchers continue to have trouble generating sufficient protein required for the crystallization process (Science, 2002). The citation of a few successful but isolated crystal structures of HCV polymerase does not help the instant applicant to overcome the overwhelming evidence provided by New Focus stating the unpredictability of the art of protein crystallization. For example, "[s]o far, these projects have targeted more than 18,000 proteins but solved the structures of only about 200" (Page 948, Column 3, lines 4-6).

18. Therefore, it is further re-iterated that it is unreasonable to expect one skilled in the art to use the information disclosed for one specific crystal to make other of predictable quality that are different from the crystal disclosed in the specification without undue experimentation.

CLAIM REJECTIONS - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to

point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 30, 31, 33, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 6,183,121 B1) in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Bressanelli et al. (1999).

22. This rejection is maintained with respect to claims 30, 31, 33, 38 and 39 as recited in the previous Office Action, mailed December 24, 2003.

RESPONSE TO ARGUMENT

23. Applicant's argument that the citation of In re Gulack has been erroneously applied. Specifically, Applicant argues that the instant invention is directed to methods of interpreting complex three-dimensional molecular structure with structural resolutions on the order of Angstroms, not printed lines and characters. Further, Applicant argues that "determining whether a test compound is complementary to said active site and/or RNA binding of said HCV polymerase...is performed differently from determining inhibitors of an HCV helicase binding pocket." Applicant's arguments have been fully considered and found to be unpersuasive as discussed below.

24. Specific to the argument that the instant invention is directed to methods of interpreting complex three-dimensional molecular structure with structural resolutions on the order of Angstroms, not printed lines and characters, Applicant is directed Table 2 (beginning on page 26) of the instant wherein the complex three-dimensional molecular structure with structural

resolutions on the order of Angstroms are printed lines and characters to be interpreted by the claimed method.

25. Specific to the argument that "determining whether a test compound is complementary to said active site and/or RNA binding of said HCV polymerase...is performed differently from determining inhibitors of an HCV helicase binding pocket", Kim et al. discloses the method steps for identifying an inhibitor from using the three-dimensional coordinates of a polypeptide as required by the instant claims. As noted in the previous Office Action, Kim et al. does not specify that the three-dimensional structural coordinates be derived from a NS5B HCV polymerase as required by the instant method claims. However, the specific limitation of three-dimensional structural coordinate being derived from a HCV polymerase in this instant case does not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter.

26. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in term of patentability. Also, the MPEP indicates that descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(b)). Specific to the instant case, the three-dimensional structural coordinates derived from a HCV polymerase of a method for identifying a HCV polymerase inhibitor are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the active steps of the method for identifying a HCV polymerase inhibitor, then

such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

27. Further, Applicant's argument that claims "38 and 39 as amended do not recite an NS5B...X is amino acid residue 531" has been considered and found to be unpersuasive because claim 39 or 39 are dependent from either claim 30 or 33, respectively, therefore, embodies all the limitation of either claim 30 or 33.

28. Specific to Applicant's argument of no motivation to combine the references of Bressanelli et al. and Kim et al., Kim et al. discloses that "[a]n understanding of such associations will help lead to the design of drugs having more favorable associations with their target receptor or enzyme, and thus, improved biological effects. Therefore, this information is valuable in designing potential inhibitors of the binding sites of biologically important targets" (column 6, lines 23-29). The polypeptide, NS3 helicase, of Kim et al. is a derivative of NS5B HCV polymerase (column 1, lines 47-67). Therefore, one of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Kim et al. for a method that uses molecular design techniques to identify, select and design chemical entities, including inhibitory compounds based on the 3-dimensional structure of a polymerase (Column 14, lines 27-38) and apply such method to the crystal structure for RNA-dependent RNA polymerase of hepatitis C virus as disclosed by Bressanelli et al.

29. Specific to Applicant's argument of "no reasonable expectation of success", said argument is directed to the difference in the way data used in the respective methods of Kim et al. and Bressanelli et al. have been obtained. Kim et al. discloses that "a computer which,

when programmed with at least a portion of the structural coordinates of HCV NS3 helicase and an X-ray diffraction data set of a different molecule or molecular complex, performs a Fourier transform of these structural coordinates of the helicase coordinates and then processes the X-ray diffraction data into structure coordinates of the different molecule or molecular complex via the process of molecular replacement." Further, Kim et al. discloses the polypeptide, NS3 helicase, is a derivative of NS5B HCV polymerase (column 1, lines 47-67). The disclosure cited above suggests that one of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success from combining the disclosure of Kim et al. and Bressanelli et al. in a method for identifying inhibitors of based on HCV helicase or HCV polymerase structure data.

REJECTION RE-ITERATED

30. It is re-iterated that Kim et al. discloses a method that uses "atomic coordinates of all the amino acids of NS3 helicase according to FIG. 1 .+-. a root mean square deviation from the backbone atoms of said amino acids of not more than 1.5 .ANG., to generate a three-dimensional structure of molecule comprising a NS3 helicase-like binding pocket, as in instant claim 30.

31. For the first time, the present invention permits the use of molecular design techniques to identify, select and design chemical entities, including inhibitory compounds, capable of binding to NS3 helicase-like binding pockets—in particular, the oligonucleotide binding pocket of NS3 helicase" (Column 14, lines 27-38), as instant claims 31 and 33.

32. "Thus, any compound which fits into a pocket comprising the structural coordinates .+-. a root mean square of 1.5 .ANG. or less from the backbone atoms of these amino acids is a

potential inhibitor of the NS3 helicase" and data disclosed in Table 1 suggest the inhibitory nature of potential inhibitors (Column 31, 36-45 and Table 1), as in claims 38 and 39.

33. Even though the method disclosed by Kim et al. does not specify that the three-dimensional structural coordinate is derived from a HCV polymerase, the specific limitations of three-dimensional structural coordinate is derived from a HCV polymerase in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter. Further, the Examiner has interpreted the instant claimed invention as a computer implemented method (pages 24-25).

34. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in term of patentability. Also, the MPEP indicates that descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(b)). Specific to the instant case, the three-dimensional structural coordinates derived from a HCV polymerase of a method for identifying a HCV polymerase inhibitor are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the active steps of the method for identifying a HCV polymerase inhibitor, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

35. Bressanelli et al. discloses a crystal structure of the RNA-dependent RNA polymerase of hepatitis C virus where the catalytic domain of the HCV RdRp consists of the 531 amino-

terminal residues of NS5B. As a key step to developing specific anti-HCV drugs that interfere with viral replication (Page 13034, lines 23-26).

36. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Kim et al. for a method that uses of molecular design techniques to identify, select and design chemical entities, including inhibitory compounds based on the 3-dimensional structure of a polymerase and apply such method to the crystal structure for RNA-dependent RNA polymerase of hepatitis C virus as disclosed by Bressanelli et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method taught by Kim et al. with the crystal structure coordinates of the RNA-dependent RNA polymerase of hepatitis C virus disclosed by Bressanelli et al. for identifying a HCV polymerase inhibitor.

CLAIM REJECTIONS - 35 USC § 103

37. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

38. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the

time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

39. Claims 30, 31, 33, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 6,183,121 B1) in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983).

40. This rejection is maintained with respect to claims 30, 31, 33, 38 and 39 as recited in the previous Office Action, mailed December 24, 2003.

RESPONSE TO ARGUMENTS

41. Applicant's arguments of "Kim does not teach all the recited claim limitations" and "no reasonable expectation of success" have been fully considered and found to be unpersuasive as discussed above.

REJECTION RE-ITERATED

42. Kim et al. discloses a method that uses "atomic coordinates of all the amino acids of NS3 helicase according to FIG. 1 .+-. a root mean square deviation from the backbone atoms of said amino acids of not more than 1.5 .ANG., to generate a three-dimensional structure of molecule comprising a NS3 helicase-like binding pocket. The polypeptide, NS3 helicase, of Kim et al. is a derivative of NS5B HCV polymerase (column 1, lines 47-67), as in instant claim 30.

43. For the first time, the present invention permits the use of molecular design techniques to identify, select and design chemical entities, including inhibitory compounds, capable of binding to NS3 helicase-like binding pockets—in particular, the oligonucleotide binding pocket of NS3 helicase" (Column 14, lines 27-38), as instant claims 31 and 33.

44. "Thus, any compound which fits into a pocket comprising the structural coordinates .+-. a root mean square of 1.5 .ANG. or less from the backbone atoms of these amino acids is a potential inhibitor of the NS3 helicase" and data disclosed in Table 1 suggest the inhibitory nature of potential inhibitors (Column 31, 36-45 and Table 1), as in claims 38 and 39.

45. Even though the method disclosed by Kim et al. does not specify that the three-dimensional structural coordinate as specified by the instant claims, the specific limitations of three-dimensional structural coordinate is derived from a NS5B HCV polymerase in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter. Further, the Examiner has interpreted the instant claimed invention as a computer implemented method (pages 24-25).

46. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in term of patentability. Also, the MPEP indicates that descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(b)). Specific to the instant case, the three-dimensional structural coordinates derived from a HCV polymerase of a method for identifying a HCV polymerase inhibitor are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the active steps of the method for identifying a HCV polymerase inhibitor, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

47. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Kim et al. for a method that uses of molecular design techniques to identify, select and design chemical entities, including inhibitory compounds based on the 3-dimensional structure of a polymerase such a derivative of a NS5B HCV polymerase. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method taught by Kim et al. with the crystal structure coordinates of the NS5B HCV derivative for identifying a HCV polymerase inhibitor.

CONCLUSION

48. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

49. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

50. This application contains claims 19-29,32 and 34-36 drawn to an invention nonelected with traverse, filed October 30, 2001. A complete reply to the final rejection must include

cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

51. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

53. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

54. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

C. Dune Ly
6/8/04

Ardin H. Marschel 6/11/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER